

Problem Description

According to the 2010 Behavioral Risk Factor Surveillance Survey, 16.7% of veterans have diabetes, almost twice the prevalence of 7.9% in the civilian population¹. Management of diabetes, both Type 1 and Type 2, requires testing of blood glucose several times a day to monitor fluctuations in blood glucose and allow administration of proper treatment. The process of glucose testing involves inserting a test strip into a glucose meter, pricking a finger with a lancing device, and then applying a drop of blood to the test strip to obtain a glucose measurement (Figure 1). Poorly controlled blood glucose leads to a higher risk of developing devastating long-term complications such as diabetic nephropathy, neuropathy, retinopathy, and limb loss.



Figure 1: Glucose Testing Video²: <https://www.youtube.com/watch?v=rMMpeLLgdgY>

Existing designs of glucose meters and lancing devices are intended for use by patients with reasonable dexterity in both hands, requiring manipulation of small components and buttons. Self-administration of glucose testing becomes very difficult when the patient does not have full function in one or both hands (Figure 2).

- One-handed insertion of a test strip into the glucose meter is difficult, due to the amount of force required to insert the strip combined with the tendency for the meter to move around unless held down or otherwise secured. Similarly, application of blood to the test strip after lancing may be complicated by tendency of meter to shift around.
- Operation of the lancing device requires that it be held and manipulated by an intact hand, as most designs require twisting actions or pressing of buttons to trigger the pricking mechanism. These actions make it impossible to trigger the lancing device while it is held in a split hook prosthetic. This makes it necessary to test blood glucose at an alternate site (thigh, forearm, etc.), since the fingers of the intact hand are not available for testing.
- Testing at alternate, or “lagging”, sites requires the use of meters that are equipped for alternate site testing, and results in glucose measurements that may not be as accurate as fingertip testing. A

glucose reading from an alternate site can give a reading that is lagging by up to 20 - 30 minutes, resulting in an unreliable measurement during unstable glucose states, such as after meals or when glucose is dropping quickly (leading to dangerous hypoglycemia)³.

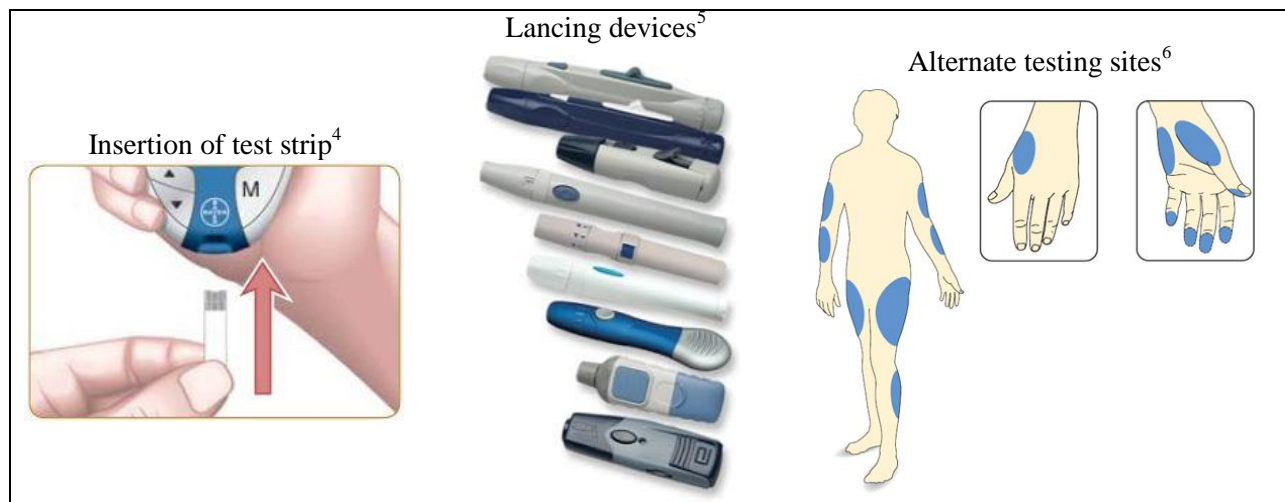


Figure 2: Challenges of Glucose Testing

Due to these challenges, veterans with upper extremity amputations may require an assistant or caretaker to perform glucose testing several times a day to achieve control of their diabetes. Therefore, our design effort was focused on creating assistive devices that would allow veterans with diabetes to self-administer glucose tests while using a split hook prosthetic. The ability to independently perform glucose testing would give veterans more control, convenience, and portability, allowing them to test whenever and wherever they need to. More ease in monitoring of glucose levels would hopefully translate into better long-term control of glucose, and a decreased risk for complications of diabetes.

Solution Description

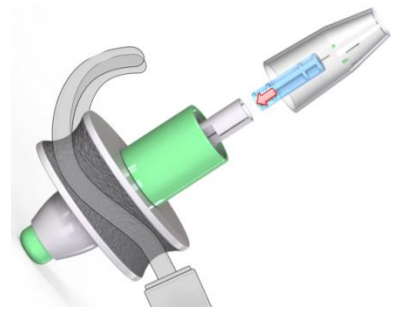
When developing a solution, we chose to design accessories to be used together with a split hook terminal device, rather than a different terminal device to be used in place of the split hook. After researching the split hook design, we decided that we wanted to allow the user to retain the advantages offered by the split hook, including durability and lightness, the ability to grasp small objects, the ability to see what is being held, and the amount of practice that amputees would have accumulated in using the split hook design⁷. Also, the use of assistive accessories rather than screw-on attachments would eliminate the need for the veteran to swap terminal devices each time glucose testing was necessary, bypassing a time-consuming and potentially cumbersome process.

Adapted Lancing Device

The Adapted Lancing Device can be held and manipulated with a split hook prosthetic and incorporates pressure-triggered lancing, allowing the user to prick and obtain blood from the fingertips of an intact hand. This eliminates the dangers of testing at alternate lagging sites, and allows instead for testing at fingertips, the most accurate and ideal testing site.

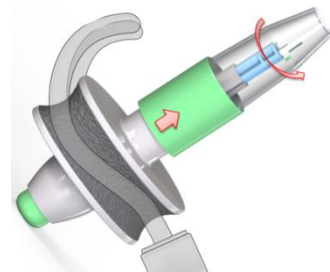
Loading a lancet

The gripping area of the lancing device has a rubber surface, allowing the user to hold it securely with a split hook. With the device held in the split hook of the amputated arm, the cap of the device is removed and the lancet loaded with the intact hand.



Cocking the device

With the device held in the split hook, the body of the device is pulled forward and then released to cock the pricking mechanism. Requiring the extra step of cocking the device is a safety consideration that prevents accidental needlestick injuries.



Triggering the device

The puncture depth can be adjusted by twisting the top part of the cap with the intact hand while holding the device in the split hook. Utilizing a mechanism similar to the auto-injection mechanism used in EpiPen® Auto-Injector devices⁸, pressure on the tip of the lancing device will trigger the fingerprick action. With the device held in the split hook, the tip can be pressed against a fingertip of the intact hand, which will cause the lancet to prick the finger and then retract back into the body of the device. The tip of the device should be pressed, released, pressed, and released several times on the pricked site until a sufficiently large drop of blood is visible through the clear tip. The blood can then be applied to the test strip to obtain a glucose measurement.



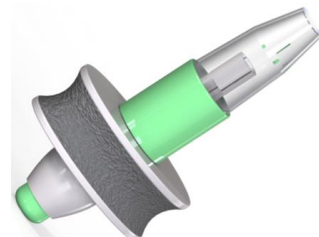
Ejection of lancet

With the device held in the split hook, the cap can be removed with the intact hand. The button at the back of the device is pressed to eject the used lancet for disposal, and the cap is replaced so the device can be stored.



Storage

The width of the Adapted Lancing Device is larger than the widths of most commercially available lancing devices, to allow easy gripping with a split hook, but still small enough to where it can be easily stored and carried.

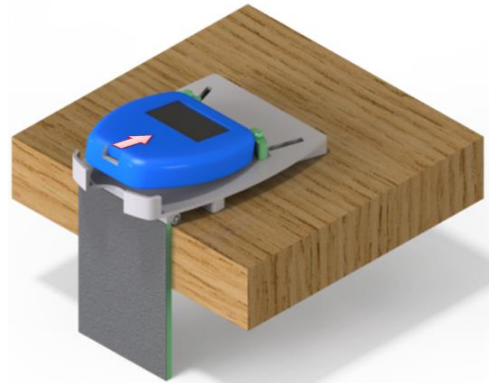


Glucose Meter Holder

The Glucose Meter Holder is intended for use with the veteran's existing glucose meter, and functions as an adaptor which stabilizes and holds the meter still so that one-handed operation becomes more feasible.

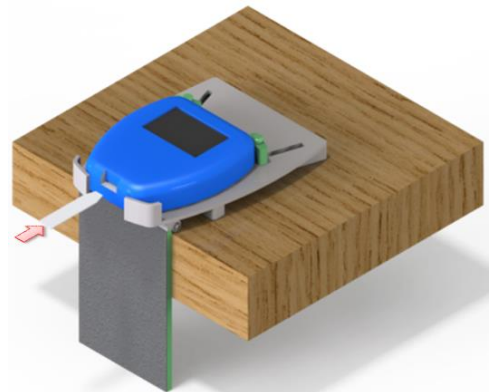
Securing meter in holder

The hinged flap flips down, allowing the user to set the holder against the edge of a surface, such as a table. The support offered by the edge of the surface keeps the glucose meter still. Alternatively, if the edge of a surface is not available, the large grippy rubber surface of the underside of the hinged flap allows the holder to keep the glucose meter still on a surface. The user inserts the glucose meter by pushing the top edge against two spring-loaded tabs; the travel distance of the tabs allows for use with a variety of glucose meters of various sizes and profiles. The meter is then laid down onto the surface of the holder, and the tension from the springs holds it in place.



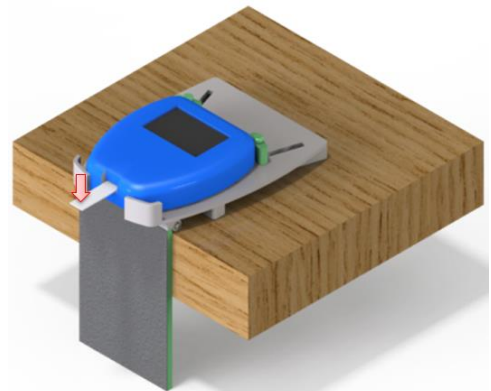
Insertion of test strip

Now that the glucose meter is secured, the test strip can be inserted with one hand.



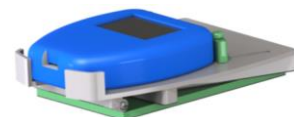
Application of blood

After pricking with the lancing device, the fingertip blood drop can be easily applied to the test strip and the glucose measurement read.



Storage

The hinged flap can be flipped closed after usage, and the glucose meter can be stored clipped onto the holder. The slim profile and compact size allows for easy storage and portability.



Incorporation of the Glucose Meter Holder and the Adapted Lancing Device into glucose testing allows veterans with upper extremity amputations to manage the entire procedure themselves, resulting in better control and management of diabetes. Additionally, the concept of creating assistive accessories for use with existing devices and split hook prosthetics can be applied to other challenges encountered by amputees. The split hook design seems to offer many advantages as a durable, functional terminal device that allows the user to accomplish a wide variety of tasks. Rather than modifying the terminal device to compensate in areas where the split hook design is unable to accomplish a specific task, design efforts can instead be directed towards modifying the objects to be manipulated until they allow for compatibility with a split hook device. This would allow the amputee to retain the advantages of using the split hook, avoid having to swap out terminal devices multiple times a day, and yet still manipulate the objects needed to accomplish desired tasks.

References

1. Hoerster KD, Lehavot K, Simpson T, McFall M, Reiber G, Nelson KM. Health and Health behavior Differences: U.S. Military, Veteran, and Civilian Men. *Am J Prev Med*. 2012; 43(5): 483-489.
2. How to test your blood glucose (sugar) levels. Diabetes.co.uk. <https://www.youtube.com/watch?v=rMMpeLLgdgY>. Updated Dec. 3, 2010. Accessed June 25, 2015.
3. Alternate Blood Glucose Testing on Arm, Palm, and Thigh. BD Diabetes Learning Center. <https://www.bd.com/us/diabetes/blood-glucose-monitoring/how-to-test/alternate-site/>. Accessed June 25, 2015.
4. Image: http://offers.bayerdiabetes.com/images/email/FAQ/Images/Contour/Results/q05/control-05_01.jpg
5. Image: <http://2.bp.blogspot.com/-yDqJwyfgI8I/UjEiKbA7QWI/AAAAAAAAAcY/OLkBMPFzDeU/s320/lancing-devices.jpg>
6. Image: <http://education.betterlivingnow.com/topic/Diabetes/media/AlternateSiteTesting2.jpg>
7. Prosthetic Devices for Upper-Extremity Amputees. Amputee Coalition of America in Partnership with the U.S. Army Amputee Patient Care Program. <http://www.amputee-coalition.org/military-instep/prosthetic-devices-upper.html>. Updated Dec. 7, 2014. Accessed June 25, 2015.
8. About EpiPen® (epinephrine) Auto-Injector. Mylan Specialty. <https://www.epipen.com/about-epipen>. Accessed June 25, 2015.